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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/747,619 12/22/00 RYAN

W 1003-015

EXAMINER

025215 HM12/0914
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ART UNIT

PAPER NUMBER

1641

DATE MAILED:

09/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/747,619

Applicant(s)

RYAN ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,9-11 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 9-11 and 35-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The Examiner of Record of the instant application has been changed from Terri McCaa to Bao-Thuy Nguyen. Any questions concerning this or any other office action may be directed to Examiner Nguyen at the telephone number listed below.
2. All rejections not reiterated herein below are withdrawn.

Amendment

3. Applicant's amendment filed 09 July 2001 has been received. Claims 2-4, 6-8 and 12-34 have been canceled. Claims 39 and 40 have been added.
4. Claims 1, 5, 9-11 and 35-40 are pending.

Drawings

5. Formal drawings have been received. However, any corrections that may be required by the draftsman can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 5, 9-11 and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US Patent No. 5,529,933) in view of Ryan (US Patent No. 5,460,797).

Young et al disclose a hematology control reagent composition comprising an aqueous solution of plasma substance. The composition is ^{used}utilized as a carrier for red blood cells and fixed white blood cells or analogs thereof in a control product that is used for quality control of particle counters such as in flow cytometry. Young et al disclose that when the composition is subject to a lytic reagent, the composition permits the lytic reaction to occur for the red blood cells in the control product. See column 6, lines 20-56. Young et al teach that fresh red blood cells samples may be treated with a composition comprising serum substances as a processing

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aid. Serum substances comprise cholesterol, cholesterol esters, lipoprotein and phospholipids and mixtures thereof. See column 8, lines 11-57. Young et al also disclose saponin based lytic system in the composition. See column 12, lines 52-55; and column 13, lines 17-20. Specifically, Young et al disclose a composition for preparing leukocytes in whole blood comprising a lytic agent, a fixative such as formaldehyde, a serum component and a suitable stabilizer.

Young et al differ from the instant invention in failing to teach the use of a preservative comprising diazolidinyl urea, imidazolidinyl and oxazolidine.

Ryan discloses a fixative solution for tissue cells comprising suspending material to be fixed or stabilized in an agent comprising diazolidinyl urea, imidazolidinyl urea and oxazolidines, etc. See column 3, lines 18-60. ^{Ryan}Young specifically disclose that the agents are preferred over formaldehyde and that the agents have extremely low toxicity, low flammability and thus do not present a fire hazard. See column 4, lines 13-57. Ryan also discloses a leukocyte positive control check for antigen-antibody studies in flow cytometry. See column 10, lines 44-65 and column 11, lines 7-58.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the stabilizers taught by Ryan in the composition of Young et al because Ryan clearly teaches the advantages of using diazolidinyl urea, imidazolidinyl and oxazolidine instead of the formaldehyde taught by Young et al. Specifically, the agents have extremely low toxicity, low flammability and thus do not present a fire hazard. The agents are also advantageous because of their ability to preserve antigenic properties of the samples being evaluated. A skilled artisan would have had a reasonable expectation of success in using the diazolidinyl urea, imidazolidinyl and oxazolidine taught by Ryan in the composition of Young

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et al because Young et al teaches the use of stabilizer and preservatives including formaldehyde and Ryan teaches the advantage of DU, IDU and oxazolidine as substitute for formaldehyde.

Response to Arguments

10. Applicant's arguments with respect to the 102 and 103 rejections have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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September 13, 2001